

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today  
(1) was not written for publication in a law journal and  
(2) is not binding precedent of the Board.

Paper No. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

**MAILED**

MAY 31 2000

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

PAT. & T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES

Ex parte EUGENE P. GOLDBERG and JAMES W. BURNS

Appeal No. 1998-2824  
Application No. 08/485,832

HEARD: May 17, 2000

Before ABRAMS, MCQUADE, and BAHR, Administrative Patent Judges.

ABRAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal from the decision of the examiner finally rejecting claims 11 and 13. Claims 1-10, 12 and 14 have been canceled. No claims have been allowed.

The appellants' invention is directed to a surgical article (claim 11) and to a bioprosthesis (claim 13). Claim 11 is illustrative of the inventive subject matter:

11. A surgical article having surfaces adapted for contacting tissue surfaces during surgery, said surfaces of said surgical article having a wet coating thereon, said wet coating comprising a physiologically acceptable aqueous solution of a hydrophilic, polymeric material wherein:

A) said polymeric material is a water-soluble, biocompatible, pharmaceutically acceptable polypeptide, polysaccharide, excluding hyaluronic acid, synthetic polymer, salt, complex or mixture thereof having a molecular weight above about 1,500,000; and

B) said polymeric material has a molecular weight of about 50,000 D or above, and the concentration in said aqueous solution of said polymer is in the range of from about 0.01% to about 15% by weight, said molecular weight and concentration having values such that said aqueous solution is capable of providing wet coatings on said surfaces; or

a physiologically acceptable aqueous solution of a hydrophilic, polymeric material, wherein:

I) said polymeric material is a water-soluble, biocompatible, pharmaceutically acceptable hyaluronic acid having a molecular weight above about 1,500,000, salt, complex or mixture thereof; and

II) the concentration in said aqueous solution of said hyaluronic acid, salt or complex is in the range of from about 0.01% to less than about 1% by weight, said molecular weight and concentration having values such that said aqueous solution is capable of providing wet coatings on said surfaces.

THE REFERENCES

The references relied upon by the examiner to support the final rejection are:

|                             |           |   |
|-----------------------------|-----------|---|
| Halpern et al.<br>(Halpern) | 4,657,820 | Apr. 14, 1987                                     |
| Nimrod et al.<br>(Nimrod)   | 4,784,990 | Nov. 15, 1988<br>(filed Jan. 18, 1985)            |
| Guire                       | 4,979,959 | Dec. 25, 1990<br>(filed May 5, 1989) <sup>1</sup> |

THE REJECTIONS

Claims 11 and 13 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the appellants regard as the invention.

Claims 11 and 13 also stand rejected under 35 U.S.C. § 103 as being unpatentable over Guire in view of Halpern and Nimrod.

Rather than attempt to reiterate the examiner's full commentary with regard to the above-noted rejections and the conflicting viewpoints advanced by the examiner and the appellants regarding the rejections, we make reference to the

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<sup>1</sup> According to the file history, the earliest effective filing date for subject matter in the appellants' application is May 31, 1988. While the application from which the Guire patent issued was filed on May 5, 1989, it was a continuation of an application filed on Oct. 17, 1986. The appellants have not challenged the examiner's use of Guire as a reference.

Examiner's Answer (Paper No. 18) and the Appellants' Briefs (Papers No. 15 and 19).

OPINION

*The Supplemental Reply Brief*

As a preliminary matter, we point out that on May 17, 2000, upon the conclusion of the oral hearing, the appellants' counsel filed at the Board of Patent Appeals and Interferences a paper captioned "SUPPLEMENTAL REPLY BRIEF," which consisted of three pages of text to which were appended copies of five United States patents. However, we will not consider this paper and/or its attachments in the course of arriving at a decision in this case, for two reasons. First, if the paper constitutes a "reply brief," it must be excluded from consideration because the appellants are limited by 37 CFR § 1.193(b)(1) to a single reply brief filed in response to an examiner's answer, and they already have availed themselves of this opportunity by virtue of having filed Paper No. 19. Second, if in the alternative, the paper is categorized as presenting exhibits submitted after the case has been appealed, we exclude it from consideration on the basis of a lack of good and sufficient reason why it was not earlier presented, since four of the five patents cited issued well before the date the paper was filed (1992-1997) and thus could

have been presented earlier in the prosecution of the present application (see 37 CFR § 1.195).

*The Rejection Under 35 U.S.C. § 112, Second Paragraph*

It is the examiner's view that claims 11 and 13 are indefinite because it is not clear exactly to what substances the limitation "having a molecular weight above about 1,500,000" applies (Answer, page 4). The appellants' argument in response is that the meaning of this portion of the claim is clear when one considers the specification, the prosecution and the amendment that was refused entry. However, we find ourselves in agreement with the examiner that the language presently recited in claims 11 and 13 is indefinite, and we therefore will sustain this rejection.

The appellants' claims are directed to a surgical article or bioprosthesis which has a wet coating thereon which comprises a physiologically acceptable aqueous solution of a hydrophilic, polymeric material having several properties. Those properties were described in the summary of the invention on page 9 of the specification, and in original claims 11 and 13, in terms that:

    said polymeric material is a water-soluble, biocompatible, pharmaceutically acceptable polypeptide, polysaccharide, excluding hyaluronic acid having a molecular weight above about 1,500,000, synthetic polymer, salt, complex or mixture thereof.

As we understand the examiner's rejection of claims 11 and 13 in the first office action, it was on the basis that it was not clear whether, in the above-quoted paragraph, only the hyaluronic acid was modified by the term "excluding," or whether this term applied to the hyaluronic acid and each of the synthetic polymer, salt, complex, or mixture thereof. In response to this rejection, the appellants then amended the claims to their present form, setting forth the properties in terms of:

said polymeric material is a water-soluble, biocompatible, pharmaceutically acceptable polypeptide, polysaccharide, excluding hyaluronic acid, synthetic polymer, salt, complex or mixture thereof having molecular weight above about 1,500,000.

This changed the location in the paragraph of the phrase "having a molecular weight above about 1,500,000," and the appellants argued that this "make[s] it clear that it is the hyaluronic acid, synthetic polymer, salt, complex and mixtures thereof which are excluded" (Paper No. 8, page 4). However, when the examiner maintained in the final rejection that the indefiniteness issue remained (now expressed as above in the opening paragraph of this section of our decision), the appellants replied with a different argument, now stating that "it is clear that the claims only exclude hyaluronic acid as a suitable polysaccharide," with no mention being made of the other elements that previously were

argued were clearly excluded (Brief, page 16). The Reply Brief sets forth yet another interpretation of the same language, opining that it is clear that "the active ingredient is a polypeptide, polysaccharide, synthetic polymer or mixture having a molecular weight above 1,500,000, but that where the active agent is the polysaccharide, hyaluronic acid, the molecular weight thereof is not above 1,500,000" (pages 1 and 2). Not only is this the first time there was mention of hyaluronic acid having a molecular weight of less than 1,500,000, but "salt" and "complex," which also appear in the claims, are omitted, although they were included in the argument in response to the first office action.

Thus, two versions of the disputed paragraph of the claims are in the record, which differ only in the location of the phrase "having a molecular weight of above about 1,500,000," and three arguments have been presented which set out conflicting interpretations of what the claim language means. The record itself thus supports the examiner's conclusion that the claims are indefinite.

It has long been held that claims are considered to be definite, as required by the second paragraph of 35 U.S.C. § 112, when they define the metes and bounds of a claimed invention with

a reasonable degree of precision and particularity. See, for example, *In re Venezia*, 530 F.2d 956, 958, 189 USPQ 149, 151 (CCPA 1976). For the reasons expressed above, it is our view that claims 11 and 13 fail to meet this test on their face, and that the arguments presented by the appellants in defense of the clarity of the claim language are not persuasive.<sup>2</sup>

*The Rejection Under 35 U.S.C. § 103*

Claims 11 and 13 also stand rejected as being unpatentable over Guire in view of Halpern and Nimrod. However, when, as is the case with claims 11 and 13, no definite meaning can be ascribed to certain of the language in a claim, the subject matter does not become obvious, but rather the claim becomes indefinite. *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Since it is clear to us that considerable speculation and assumptions are necessary to determine the metes and bounds of what is being claimed in claims 11 and 13, and since a rejection under 35 U.S.C. § 103 cannot be based upon

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<sup>2</sup> We wish to point out that the description of the invention in the appellants' specification utilized the very language which the examiner decided rendered the original claims indefinite, and therefore the possibility of issues arising under 35 U.S.C. § 112, first paragraph, should be considered with regard to the expression of the invention in any new claims presented, should further prosecution of this application ensue.

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speculation and assumptions, we are constrained to reverse the examiner's obviousness rejection. *In re Steele*, 305 F.2d 859, 862-63, 134 USPQ 292, 295 (CCPA 1962). We hasten to point out, however, that this action should not be construed as an indication that the claimed subject matter would not have been obvious in view of the applied prior art. We have not addressed that issue, for to do so would require on our part the very speculation which formed the basis of our rejection under Section 112.

SUMMARY

The rejection of claims 11 and 13 under 35 U.S.C. § 112, second paragraph, is sustained.

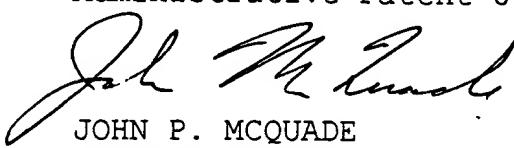
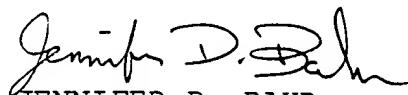
The rejection of claims 11 and 13 under 35 U.S.C. § 103 is not sustained.

A rejection of each of the claims on appeal having been sustained, the decision of the examiner is affirmed.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

  
NEAL E. ABRAMS )  
Administrative Patent Judge )  
  
JOHN P. MCQUADE ) BOARD OF PATENT  
Administrative Patent Judge )  
  
JENNIFER D. BAHR ) APPEALS AND  
Administrative Patent Judge ) INTERFERENCES

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